EPA SCIENTIFIC ADVISORY COMMITTEE ON CHEMICALS
CHARGE TO THE PANEL – ASBESTOS

As amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, the Toxic Substances Control Act (TSCA), requires the U.S. Environmental Protection Agency (EPA) to conduct risk evaluations on existing chemicals. In December of 2016, EPA published a list of the initial ten chemical substances that are the subject of the Agency's chemical risk evaluation process (81 FR 91927), as required by TSCA. Asbestos is one of the first ten chemical substances and the ninth of the ten to undergo a peer review by the Science Advisory Committee on Chemicals (SACC). In response to this requirement, EPA has prepared and published a draft risk evaluation for Asbestos. The EPA has solicited comments from the public on the draft and will incorporate them as appropriate, along with comments from peer reviewers, into the final risk evaluation.

The focus of this meeting is to conduct the peer review of the Agency's draft risk evaluation of asbestos and associated supplemental materials. At the end of the peer review process, EPA will use the reviewers' comments/recommendations, as well as public comment, to finalize the risk evaluation.

This draft risk evaluation contains the following components:

- Discussion of chemistry and physical-chemical properties
- Characterization of uses/sources
- Detailed description of the systematic review process developed by the Office of Pollution Prevention and Toxics to search, screen, and evaluate scientific literature for use in the risk evaluation process.
- Environmental fate and transport assessment
- Environmental exposure assessment
- Human health hazard assessment
- Environmental hazard assessment
- Risk characterization
- Risk determination

CHARGE QUESTIONS:

Systematic Review (Section 1.5 of the Draft Risk Evaluation):

The Toxic Substances Control Act (TSCA) requires that EPA use data and/or information in a manner consistent with the "best available science" and that EPA base decisions on the "weight of the scientific evidence". The EPA's Final Rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726), defines ''best available science'' as science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). The Final Rule also defines the "weight of the scientific evidence" as a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including the strengths, limitations, and relevance of each study and to integrate evidence

as necessary and appropriate based upon strengths, limitations, and relevance.

To meet these scientific standards, EPA applied systematic review approaches and methods to support the asbestos draft risk evaluation. Information on the approaches and/or methods is described in the draft risk evaluation as well as the following documents:

• Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document, (EPA-HQ-OPPT-2016-0736-0083)

• Asbestos (CASRN 1332-31-4) Bibliography: Supplemental File for the TSCA Scope Document, (EPA-HQ-OPPT-2016-0736-0084)

• Asbestos Problem Formulation (EPA-HQ-OPPT-2016-0736-0131)

• Application of Systematic Review in TSCA Risk Evaluations (EPA-HQ-OPPT-2016-0736-0132)

EPA has solicited peer review and public feedback on systematic review approaches and methods for prior evaluations. *A general question on these approaches is not included in this charge; however, EPA will accept comment on the systematic review approaches used for this evaluation if provided*.

1. Environmental Exposure and Release

Based on the reasonably available information in the published literature, provided by industries using asbestos, and reported in EPA databases, there is minimal or no releases of asbestos associated with the conditions of use (COUs) that EPA is evaluating in this risk evaluation.

1.1. Please comment on whether the information presented supports the analysis and conclusion in the draft environmental exposure section (Section 2.2 and Appendix D).

1.2. Please comment on whether EPA adequately, clearly and appropriately presented the physical-chemical properties/characteristics of chrysotile asbestos.

2. Occupational Exposure (Section 2.3.1)

Workers and occupational non-users may be exposed to commercial chrysotile asbestos when workers perform activities associated with several COUs:

- Asbestos diaphragms used in the chlor-alkali industry
- Asbestos-containing sheet gaskets (both stamping and use)
- Oil field brake blocks
- Aftermarket automotive brakes and linings
- Other vehicle friction products
- Other gaskets (Utility vehicles)

EPA evaluated what is known about chronic exposures to workers and occupational nonusers (ONUs) for the COUs listed above via the inhalation pathway only. The principle approach EPA used to estimate occupational exposures – for both workers and ONUs - was reviewing and interpreting monitoring data, whether provided by industry or documented in the peer-reviewed literature. EPA assumed that workers and occupational non-users would be adolescents and adults of both sexes (≥16 and older).

2.1. Please comment on the estimation methods and assumptions used for occupational exposure assessment (including ONUs) in terms of concentration, frequency and duration of exposures; and their use in the risk evaluation. Below are two specific issues in which EPA is particularly interested in feedback from the SACC

Incorporation of Short-Term Occupational Monitoring Results
EPA received from industry (or obtained from the published literature short-term (i.e., less than a full 8-hour work shift) monitoring data for several of the COUs (chlor-alkali, sheet gaskets/stamping, aftermarket automotive parts, and other vehicle friction products). For these COUs, EPA calculated a separate "full-shift" asbestos exposure estimates as well as a short-term exposure estimate to account for these occasional, short, high-exposure scenarios. Please comment on the method used.

ONU Exposure Estimates
Based on the readily available information, EPA used different methods to estimate ONU exposures. ONU estimates were made for each COU; however, the limited information did not allow the development of ONU exposures for short-term exposure scenarios for chlor-alkali, sheet gasket use, oil field brake blocks, or other gaskets/UTVs. Please comment on the method(s) used (identified below).

- Chlor-alkali (Section 2.3.1.3.5): For ONU exposure estimates area samples were used. Two chlor-alkali facilities provided a total of 15 area samples which were all below the limit of detection (LOD). There were two different detection limits in the two submissions. Although true exposure values below any limit of detection may be unevenly distributed from zero to the limit of detection, we assumed that the central tendency exposure concentration estimate is based on one-half of the detection limit for individual samples and the high-end concentration is based on the highest detection limit across the samples.
- Sheet Gasket Stamping and use (Sections 2.3.1.4.5 and 2.3.1.5.5): EPA did not identify any ONU exposure measurements for these COUs. However, the literature includes "bystander" exposure studies. Specifically, one publication (Mangold, 2006) measured "bystander" exposure during asbestos-containing gasket removal. The "bystander" locations in this study were between 5 and 10 feet from the gasket removal activity, and asbestos concentrations were between 2.5 and 9 times lower than those measured for the worker. Based on these observations, EPA assumes that ONU exposures for these COUs are a factor of 5.75 (i.e., the midpoint between 2.5 and 9) lower than the directly exposed workers.
- Oilfield brake blocks (Section 2.3.1.6.5): EPA has not identified specific data on potential ONU inhalation exposures from brake block use. It is assumed that ONUs do not directly handle brake block and drawworks machineries and that this equipment is always used and serviced outdoors close to oil wells. Given the limited information identified in Section 2.3.1.6.4 (i.e., worker monitored values), the lower of the two reported values was used to represent ONU exposures for this COU.
- Aftermarket automotive brakes (Section 2.3.1.7.5): EPA has not identified data on potential ONU inhalation exposures from after-market auto brake scenarios. ONUs do not directly handle brakes and the ONU exposure estimates in Table 2-15 were generated by assuming that asbestos concentrations decreased by a factor of 8.4 between the worker location and the ONU location. EPA derived this reduction

factor from a publication (Madl, 2008) that had concurrent worker and bystander exposure measurements where the bystander was approximately 5 feet from the worker. The value of 8.4 is the average concentration reduction across four concurrent sampling events.

- Other gaskets/UTVs (Section 2.3.1.9.4): Paustenbach (2006) includes area sampling results that EPA thought appropriate for ONU exposures. These samples were collected at breathing zone height at locations near the ends of the muffler shop bays where the exhaust system work was performed. The area sample durations ranged from 25 to 80 minutes, and these samples were collected during exhaust system work. Overall, 21 area samples from these locations were analyzed by PCM; and 16 of these samples were non-detects for asbestos. Among the PCM data from this subset of area samples, the authors report that the average asbestos concentration was 0.005 fibers/cc and the maximum asbestos concentration was 0.015 fibers/cc. The study authors did not report 8-hour TWA concentrations for the area sample locations. EPA used these average and maximum asbestos concentrations to estimate potential ONU exposures.

2.2. Please comment on EPA's reasonableness of these assumptions, the uncertainties they introduce, and the resulting confidence in the occupational exposure estimates (Section 4.3.3).

2.3. Please provide specific suggestions or recommendations for alternative approaches, estimation methods, or information sources that EPA should consider for improving the occupational exposure assessment.

3. Consumer Exposure (Section 2.3.2)

Consumers (Do-it-Yourselfers, or DIY, or DIY mechanics) and bystanders may be exposed to commercial chrysotile asbestos when consumers perform activities associated with several COUs:

- Aftermarket automotive brakes and linings
- Other Gaskets (Utility vehicles - UTVs)

3.1. Please comment on the estimation methods and assumptions used for consumer/DIY exposure assessment (including bystanders) in terms of concentration, frequency and duration of exposures; and their use in the risk evaluation. Please include your thoughts on the reasonableness of the estimated age at start of exposure and duration and frequency of exposure for the consumer (DIY and bystander) (Section 4.2.3).

3.2. Please comment on EPA's approach to developing consumer/DIY exposure estimates for aftermarket automotive brakes/linings (Section 2.3.2.1). Please include your thoughts on the reasonableness of the estimated age at start of exposure and duration and frequency of exposure for the consumer (DIY and bystander) (Section 4.2.3).

3.3. Please comment on EPA's approach to developing bystander exposure estimates (specifically the use of reduction factors [RFs] (Sections 2.3.2.1 and 2.3.2.2).

3.4. Please comment on EPA's approach to develop consumer/DIY exposure estimates for other gaskets (UTVs) (Section 2.3.2.2).

3.5. Please comment on EPA's reasonableness of the assumptions used, the uncertainties they introduce, and the resulting confidence in the consumer exposure estimates (Section 4.3.4).

3.6. Please comment on the methods and assumptions used in approaches for the sensitivity analysis for the consumer (DIY and bystander) risk estimates for both aftermarket automotive brakes and UTV gaskets (Appendix L).

3.7. Please provide any specific suggestions or recommendations for alternative approaches, estimation methods, assumptions, or information that should be considered by the Agency for improving the consumer exposure assessment.

4. Human Health Hazard/Derivation of the Inhalation Unit Risk (IUR)

EPA derived the chrysotile-based inhalation unit risk (IUR) based on a review of the epidemiology literature describing occupational cohorts exposed to commercial chrysotile that provided adequate data for assessment of lung cancer and mesothelioma risks. Cancer potency values were either extracted from published epidemiology studies or derived from the data within those studies. Once the cancer potency values were obtained, they were adjusted for differences in air volumes between workers and other populations so that those values can be applied to the U.S. population as a whole in the standard EPA life-table analyses. The life-table methodology allows the estimation of an exposure concentration association associated with a specific extra risk of cancer mortality caused by commercial chrysotile asbestos. According to standard practice, the lifetime unit risks for lung cancer and mesothelioma were estimated separately and then statistically combined to yield the cancer inhalation unit risk.

Less-than-lifetime or partial lifetime unit risks were also derived for a range of exposure scenarios based on different ages of first exposure and durations of exposure.

4.1. Please comment on EPA's choice of focusing on only lung cancer and mesothelioma.

4.2. Please comment on the appropriateness of the approach to derive the commercial chrysotile-based IURs, including the underlying assumptions, strengths and weaknesses of the choice of study cohorts used, the key calculation decisions and the modelling used to derive the IUR (Section 3.2.4).

4.3. Please comment on EPA's approach to characterizing the implications of the assumptions and uncertainties for the confidence associated with the derivation of the IURs (Section 4.3.5).

4.4. Please provide any specific suggestions or recommendations for alternative approaches that should be considered by the Agency in deriving the commercial chrysotile-based IUR.

5. Human Health Risk Characterization

EPA posited that there were minimal or no releases of asbestos to surface water associated with the conditions of use (COUs) evaluated in this risk evaluation and thus concluded there is no risk to aquatic or sediment-dwelling organisms (Section 4.1).

As discussed above, EPA calculated the potential for extra cancer risk via inhalation exposures for occupational (workers and ONUs) and consumers (DIYers and bystanders) for cancer effects. The risk characterization provides a discussion of the uncertainties surrounding the risk calculations.

On the basis of the estimated exposure and risks, EPA concluded that inhalation of chrysotile asbestos presents an unreasonable risk of injury to workers (and ONUs) and consumers (and bystanders) (See Section 4.2.). EPA also concludes that asbestos does not present an unreasonable risk to environmental receptors exposed via surface water (see Section 4.1). EPA makes this determination considering risk to potentially exposed and susceptible subpopulations identified as relevant, under the conditions of use without considering costs or other non-risk factors.

5.1. EPA presented overall human health risk conclusions (Sections 4.5.2 and 4.5.3) based on risk estimates for cancer. Please comment on EPA's approach including any alternative considerations for assessing and presenting risk conclusions including the risk summary tables (Table 4-55 and 4-56).

5.2. Please comment on the clarity and validity of specific confidence summaries presented in Section 4.3.

5.3. Throughout this charge we have asked reviewers to comment on the uncertainties and data limitations associated with the methodologies used to assess the environmental and human health risks. Please comment on whether that information has been carried forward to the characterization of the risk evaluation such that the strength of the unreasonable risk conclusions is characterized in a clear and transparent manner (Section 4.3).

5.4. Please comment on whether the analysis presented in Section 4 supports the conclusions for both the environment (Section 4.5.1) and human health (Section 4.5.2 and 4.5.3) in the draft risk characterization section concerning asbestos. If not, please explain the limitations of these conclusions, and whether there are alternative approaches or information that could be used to further develop the risk estimates within the context of the requirements stated in EPA's Final Rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726) (Section 4).

5.5. Please comment on any other aspect of the environmental or human health risk characterization that has not been mentioned above (Section 4).

6. Additional Questions:

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016) (amended TSCA) states that "potentially exposed or susceptible subpopulations" (PESS) be considered in the risk evaluation process. PESS is defined in the Lautenberg Act to include populations with greater exposure or greater response, including due to lifestyle, dietary, and biological susceptibility factors, than the general population.

6.1. Has a thorough and transparent review of the available information been conducted that has led to the identification and characterization of all PESS (Sections 2.3.3, 3.2.5., and 4.4.1)? Do you know of additional information about PESS that EPA needs to consider? Additionally, has the uncertainty around PESS been adequately characterized?

The EPA risk characterization of human health risk from inhalation exposure to workers includes estimates of risk for respirator use. EPA was supplied information on respirator use from some industry representatives. EPA estimated cancer risks based on no use of respirators and with respirators by the respirator assigned protection factors (APFs) of 10 and 25. EPA did not assume occupational non users (ONUs) or consumers used personal protective equipment in the risk estimation process.

6.2. Please comment on whether EPA has adequately, clearly, and appropriately presented the reasoning, approach, assumptions, and uncertainties for characterizing risk to workers using PPE (exposure - Sections 2.3.1.2.; risk Section 4.2.1 and Tables 4-3 and 4-38).

6.3 Please comment on whether EPA has adequately, clearly, and appropriately presented the reasoning, approach, assumptions, and uncertainties for characterizing risk to ONUs who would not be expected to use PPE (Sections 4.2.1 and 4.3.7).

7. Overall Content and Organization

EPA's Final Rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726) stipulates the process by which EPA is to complete risk evaluations under the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

As part of this draft risk evaluation for asbestos, EPA evaluated potential environmental, occupational and consumer exposures. The evaluation considered reasonably available information, including manufacture, use, and release information, and physical-chemical characteristics. It is important that the information presented in the risk evaluation and accompanying documents is clear and concise and describes the process in a scientifically credible manner.

To increase the quality and credibility of scientific information disseminated by EPA, EPA uses the peer review process specifically as a tool for determining fitness of scientific information for the intended purpose. The questions below are intended to guide the peer reviewers toward determining if EPA collected, used and disseminated information that is 'fit for purpose' based on utility (the data's utility for its intended users and for its intended purpose), integrity (the data's security), and objectivity (whether the disseminated information is accurate, reliable, and unbiased as a matter of presentation and substance). The peer reviewers' critical focus should pertain to recommendations of the technical information's usefulness for intended users and the public.

7.1. Please comment on the overall content, organization, and presentation of the asbestos draft risk evaluation. Please provide suggestions for improving the clarity of the information presented.

7.2. Please comment on the objectivity of the information used to support the risk characterization and the sensitivity of the agency's conclusions to analytic decisions made.